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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,578	05/03/2002	Audrey Goddard	P3230R1C001-168	2392
30313 7590 05/02/2007 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET IRVINE, CA 92614			EXAMINER HOWARD, ZACHARY C	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 05/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/063,578	Applicant(s) GODDARD ET AL.	
	Examiner Zachary C. Howard	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 2/2/07 has been entered in full. The specification is amended. No claims are amended, added, or canceled.

Claims 1-5 are under consideration in the instant application.

Information Disclosure Statement

The Information Disclosure Statement of 2/2/07 has been considered.

Sequence Compliance

In response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures mailed 10/31/06, Applicants have (on 2/2/07) submitted a paper copy of the Sequence Listing, and a statement that the sequences in the paper copy are identical to the sequences in the electronic copy of Sequence Listing included in the application as filed. In view of Applicants' submissions, the application is now compliant with the requirements of 37 CFR 1.821 through 1.825.

Priority

(1) The Examiner previously stated (10/31/06; pg 3) that the record for application 10/006867 indicated that this file was actually a CIP of PCT/US00/23328, rather than a continuation as indicated in the priority statement of the instant application. In response, Applicants submit that the '867 application is a continuation of the '328 PCT "as both applications have the same specification. The Examiner has checked the record for the '867 application and notes that the continuity information was corrected by the PTO on 10/21/06 to indicate that '867 is a continuation of the '328 PCT. It appears that the inconsistency was an error on the part of the Office and the priority statement in the instant application is correct in this regard.

(2) The Examiner previously stated (10/31/06; pg 3) that the instant application only merits priority to 8/24/2000, the filing date of PCT/US00/23328 because application 09/380137 is an incomplete file that was never granted a filing or 371(c) date. In response, Applicants have amended the priority statement such that the '328 PCT is the earliest application to which the instant application claims priority. Therefore, the priority statement is now correct in this regard.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (10/31/06).

The objection to the specification at pg 5 is *withdrawn* in view of Applicants' response to the section titled "Priority" as described above.

The rejections of claims 1-5 under 35 U.S.C. § 102(a) at pg 6 as being clearly anticipated by Baker et al, WO 99/63088 (mistakenly written as WO 00/63088) is *withdrawn* in view of the Declaration of William Wood under 37 C.F.R. § 1.132 filed 2/2/07, which states that Figure 270 of WO 99/63088 is a publication of Applicants' own invention. The Examiner has fully considered the Declaration and finds it sufficient to overcome the rejection.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over NCBI Accession No. BE531149 (NCBI Accession No. BE531149, Strausberg, created August 7, 2000, updated August 9, 2000; cited in the 8/24/00 Office Action) in view of U.S. Patent No. 6,262,234 (cited in the 8/24/00 Office Action). This rejection was set forth at pg 6-7 of the 10/31/06 Office Action

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Applicants' arguments (2/2/07; pg 5-6) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response Applicants first note that Strausberg discloses a raw nucleic acid sequence obtained from adenocarcinoma but does not disclose any additional information relating to the sequence such as homology to other known sequences or information relating to the differential expression pattern of the nucleic acid.

Applicants' arguments have been fully considered but are not found persuasive. A disclosure of homology to known sequences or a differential expression pattern is not necessary for the skilled artisan to make antibodies to the novel polypeptide. NCBI BE531149 teaches a cDNA nucleic acid sequence that encodes a polypeptide that is 100% identical to SEQ ID NO: 68. The ATG representing the start codon of this protein is found at residues 15-17 of the nucleic acid sequence. The BE531149 accession number does not teach antibodies that bind to the encoded polypeptide. The '234 patent teaches monoclonal antibodies, antigen-binding fragments, humanized antibodies, and labeled antibodies for use in characterizing novel polypeptides (see column 18). It would have been obvious to a person of ordinary skill in the art to make such antibodies because it is a commonly employed laboratory technique. One of ordinary skill in the art would have been motivated to do so because such antibodies are used for further characterization of novel polypeptides. The person of ordinary skill in the art would have had a reasonable expectation of success because the '234 patent teaches the techniques necessary to produce an antibody to a novel protein. Therefore, the invention taken as a whole is *prima facie* obvious over the prior art.

Applicants further argue that Applicants' own applications (09/380137, filed 8/25/1999; PCT/US99/12252, filed 6/2/1999; and 60/090246 filed 6/22/1998) each disclose the polypeptide of SEQ ID NO: 68. Applicants' submit that BE531149 is not available as prior art "[b]ecause Applicants demonstrated, by means of disclosure in their provisional application filed 6/22/1998, that they were in possession of so much of the claimed invention as is disclosed in BE531149 prior to the publication dates of this reference..."

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Applicants' arguments have been fully considered but are not found persuasive. The rejection under 103(a) is based upon NCBI Accession No. BE531149, published August 9, 2000, which is a publication that is less than one year prior to Applicants earliest priority date (8/24/2000). Therefore, the rejection under 103(a) is based on a 102(a)-type date. As stated in MPEP 706.02(b):

"A rejection based on 35 U.S.C. 102(a) can be overcome by: (A) Persuasively arguing that the claims are patentably distinguishable from the prior art; (B) Amending the claims to patentably distinguish over the prior art; (C) Filing an affidavit or declaration under 37 CFR 1.131 showing prior invention, if the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention as defined in 37 CFR 41.203(a). See MPEP § 715 for information on the requirements of 37 CFR 1.131 affidavits. When the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not appropriate to overcome the rejection. (D) Filing an affidavit or declaration under 37 CFR 1.132 showing that the reference invention is not by "another." See MPEP § 715.01(a), § 715.01(c), and § 716.10; (E) Perfecting a claim to priority under 35 U.S.C. 119(a)-(d) as explained in reference to 35 U.S.C. 102(e) above; (F) Perfecting benefit under 35 U.S.C. 119(e) or 120 as explained in reference to 35 U.S.C. 102(e) above."

Applicants' arguments with respect to Applicants' previously filed applications do not meet any of these means of overcoming a rejection based on 102(a). If Applicants wish to demonstrate prior invention, an affidavit or declaration under 37 CFR 1.131 showing prior invention must be filed. One requirement of a 1.131 declaration is that "Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country." As stated in MPEP 715.07.III, "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of invention in this country or in a NAFTA or WTO member country (MPEP § 715.07(c)), at least the conception being at a date prior to the effective date of the reference."

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Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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